

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF)	
AMERICA, <i>et al.</i> , <i>ex rel.</i>)	
BROOKS WALLACE,)	
ROBERT FARLEY and)	
MANUEL FUENTES, <i>et al.</i>)	
)	
Plaintiffs,)	2:18-cv-01010-LSC
)	
vs.)	
)	
EXACTECH, INC.,)	
)	
Defendants.)	

MEMORANDUM OF OPINION AND ORDER

I. BACKGROUND AND LEGAL STANDARD

Before this Court is Defendant Exactech's Rule 59(e) Motion for Reconsideration (Doc. 189) of this Court's Memorandum of Opinion and Order (Doc. 184) denying their previous Motion for Summary Judgment (Doc. 143) and Motion to Dismiss (Doc. 161).¹

II. DISCUSSION

Exactech's Rule 59(e) motion primarily proffers two arguments. The Court addresses each in turn.

¹ A comprehensive factual summary of this case is contained in that opinion. (Doc. 184).

A. Whether the Public-Disclosure Bar Applies

Exactech's first argument involves the Court's previous determination that the FCA's public-disclosure bar did not apply in this case because it failed the second prong of *Cooper*. (See Memorandum Op., Doc. 184 at 12-13). Even if the Court's reasoning is flawed, the decision to deny Exactech's Motion to Dismiss was nevertheless proper because Relators satisfy the original-source exception.

The public-disclosure bar attempts to strike a balance between the FCA's goals of encouraging people with inside information to expose fraud against the government and avoiding parasitic suits brought by people that played no role in bringing fraud to light. See *U.S. ex rel. Williams v. NEC Corp.*, 931 F.2d 1493, 1497 (11th Cir. 1991). In other words, the purpose of the public-disclosure bar is to differentiate between whistleblowers and freeloaders. It functions by barring *qui tam* actions based on publicly disclosed information, unless the relator bringing that action is the original source of said information. See *U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 812 (11th Cir. 2015). A relator is an original source if their knowledge was "direct and independent" of the publicly disclosed information. *Id.* at 814. A relator is not an original source if their knowledge was mere "background information which enable[d] him to understand the significance of a more general public disclosure." *Id.* at 815.

Exactech claims multiple instances of overlapping facts between this action and the previous products liability suits filed by Cory Watson trigger the public disclosure bar. For example, Exactech cites to the fact that Relators in this *qui tam* action pleaded in their complaint: “In early 2008. . . Exactech had definitive knowledge that the [Device] was defective.” (Doc. 1 at 19). Similarly, the complaint filed by one of five plaintiffs in the products liability suits alleged: “By at least April 2008, [Exactech] became aware of a high rate of early failures with the [Device].” (Doc. 160, Ex. A at 26).

The parties agree that, because the Cory Watson lawsuits were filed before this *qui tam* action, Exactech’s awareness of the Device’s defect was publicly disclosed information. Exactech argues that because that allegation is central to this *qui tam* action, the Relators’ claims were based on that publicly disclosed information. But even if the Court accepted that argument, the public-disclosure bar would still not apply in this case if the Relators were the original source of that publicly disclosed information.

They were. All evidence before the Court demonstrates that the Relators’ knowledge of Exactech’s awareness of the Device’s defect was “direct and independent” from the publicly disclosed information. *Osheroff*, 776 F.3d at 814. The independence of the Relators’ knowledge from the public disclosures is self-

evident: Cory Watson only learned of Exactech's awareness of the Device's defect because the Relators told them.² Likewise, all evidence before the Court demonstrates that the Relators' knowledge was direct: the Relators originally learned of Exactech's awareness of the Device's defect from meetings Relator Fuentes personally attended where Exactech's "top executives and engineers" met to discuss and strategize about "data demonstrating significant device failure." (Doc. 1 at 7). This knowledge cannot be characterized as mere "background information" enabling the Relators to "understand the significance of a more general public disclosure." *Osheroff*, at 815.

The remainder of Exactech's attempts to persuade this Court that the Relators were not the original sources of other information publicly disclosed through the Cory Watson lawsuits range from unmeritorious to completely divorced from logic.³ The public-disclosure bar does not apply to this case. Exactech's Motion for this Court to reconsider this holding is due to be DENIED.

² Jon Conlin, lead attorney for Cory Watson in all five of the products-liability cases, swore under oath that the Relators were the first to tell his firm about Exactech's definitive knowledge of the defect. (Doc. 169, Ex. A). Or in legal terms, Cory Watson itself identified the Relators as their original source of the information it publicly disclosed. In fact, the Relators brought this information to Cory Watson for the very purpose of seeking representation by that firm for this *qui tam* action. See (*id.*).

³ For example, Exactech argues that the fact that Relator Farley stated that Relator Fuentes had first-hand knowledge of the Devices' widespread history of failures somehow demonstrates

B. Whether the Device is “Reasonable and Necessary”

Exactech’s second argument involves the Court’s conclusion that “the evidence viewed in the light most favorable to Relators is sufficient to demonstrate a genuine issue of material fact exists as to whether the [Device] was ‘reasonable and necessary.’” (Doc. 189 at 10 (citing Memorandum of Opinion, Doc. 184 at 22-24)). As explained in this Court’s previous opinion, the “reasonable and necessary” determination in this case comes down to the failure rate of the Device. (Memorandum Op., Doc. 184 at 22-24). Relators allege the failure rate is between 28 and 35%, and Exactech alleges the rate is less than 1%. (*Id.*).

In its Motion for Reconsideration, Exactech claims that “Relators’ own evidence proves that the true failure rate is less than 1% . . . [b]ecause Relators have identified at most 292 [failures] . . . out of 33,927 Devices *sold* during the relevant period.” (Doc. 189 at 12) (emphasis added). Exactech reached that figure by “divid[ing] the number of revisions by the total number of devices *sold*.” (*Id.* at 11) (emphasis added). There are two glaring issues with this argument.

The first issue concerns the denominator Exactech used for their failure rate calculation—the number of devices sold. Exactech provides no explanation for why

that Relator Farley lacks the same first-hand knowledge. By this logic, two persons could never have first-hand knowledge of the same event. Furthermore, Exactech fails to recognize that on the following page of Farley’s testimony, he specifically states that he too possessed first-hand knowledge. *See* (Doc. 169-5 at 4).

it used this number when this case obviously concerns the number of Devices surgically implanted into human beings. Exactech's argument only makes logical sense by assuming that the number of devices sold is equal to the number of devices surgically implanted, or that there is some sort of technical definition of a medical device's failure rate that does not ignore medical devices sitting unused on storage shelves.⁴ Exactech has proffered neither argument nor evidence supporting either of these assumptions.

The second issue concerns the process Exactech used to calculate the numerator it used for their failure rate calculation. That process reeks of sampling bias. Exactech treated the number of Device failures the Relators *identified* as the number of Device failures that have *occurred*. That is, Exactech assumed the Relators identified every single Device failure that has occurred. The Court is unwilling to accept the Relators possess such omniscience. Rather, and as is clearly implied in this Court's previous opinion, there is sufficient evidence to demonstrate a genuine issue of material fact as to whether the total number of device failures *that have occurred* is significantly greater than the number of device

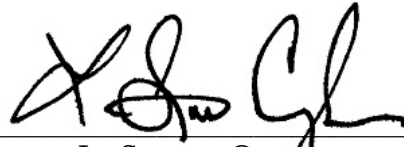
⁴ This assumption could have support if the Device were one that could not be kept as inventory, but this possibility is untenable, as Exactech's CFO's reason for not recalling the Device in the first place was due to the fact that the company was "drowning in . . . [Device] inventory." (Doc. 149-34 at 3).

failures the Relators *have specifically identified*. The true number of times the Device has failed is an issue to be determined in trial.

III. CONCLUSION

Exactech's Motion for Reconsideration (Doc. 189) is hereby DENIED.

DONE AND ORDERED ON SEPTEMBER 8, 2022.

A handwritten signature in black ink, appearing to read 'L. Scott Coogler', is written over a horizontal line.

L. SCOTT COOGLER
UNITED STATES DISTRICT JUDGE

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